NEHI Network for Excellence in Health Innovation

PRESENTS . . .

NEXT GENERATION VALUE-BASED ARRANGEMENTS IN MASSACHUSETTS: THE ROAD AHEAD

Who We Are

Approximately 70 health care organizations across the industry leveraging collaboration in meeting a critical mission

Mission: advance innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent.

Methods: gather and present research and analysis to build consensus toward actionable policies and practices

Today's Panel

ANNIE KENNEDY
Chief of Policy and Advocacy,
EveryLife Foundation for Rare Diseases

ELEANOR PERFETTO, PhD, MS
Interim Chief Executive Officer and Executive Vice President of Strategic Initiatives,
National Health Council

MICHAEL SHERMAN, MD, MBA, MS
Chief Medical Officer,
Harvard Pilgrim Health Care

DAN WYGAL
Executive Director of Contract and Channel Strategy,
AstraZeneca

Moderated by: Tom Hubbard, *VP of Policy Research*, NEHI

Massachusetts: A Novel Therapy Center

NEHI Network for Excellence in Health Innovation

The New York Times | https://nyti.ms/2hBv4Gn

Costly Drug for Fatal Muscular Disease Wins F.D.A. Approval

By Katie Thomas

Dec. 30, 2016

The Food and Drug Administration has approved the first drug to treat patients with spinal muscular atrophy, a savage disease that, in its most severe form, kills infants before they turn 2.

March 20, 2018

Press Release

Mass. Eye and Ear Performs First FDA-approved Gene Therapy Procedure for Inherited Disease

FDA approves first drug to use RNA interference, based on discoveries made at UMass Medical School

Alnylam's patisiran will help patients with rare disease

UMass Medical School Communications August 10, 2018

Novel Drug Challenge Converges in Massachusetts

Key Concerns:

- Patient access to therapy
- Affordability for patients
- Sustainable trend in insurance premiums
- Continued environment of biopharma innovation

Marylou Sudders, MA Secretary of Health and Human Services, November 7, 2018

Payers' Challenge: Launch Price and……

- Budget impact
- Actuarial risk of coverage
- Impact on year-to-year insurance premiums
- Real World effectiveness and durability
- Health care utilization associated with the therapy (example: therapies administered at FDA-certified "centers of excellence")
- Cost and administrative burden of alternative contract methods

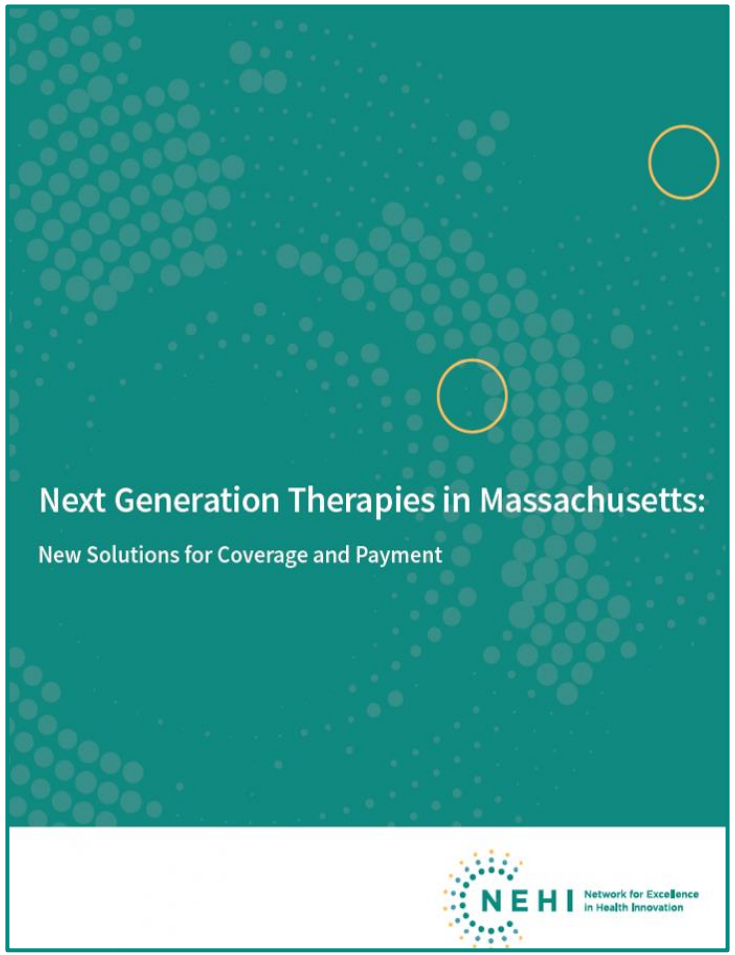
Oct. 3, 2019

Prime Therapeutics Study Reveals 60% Surge in Number of People Taking Ultra Expensive Medicines

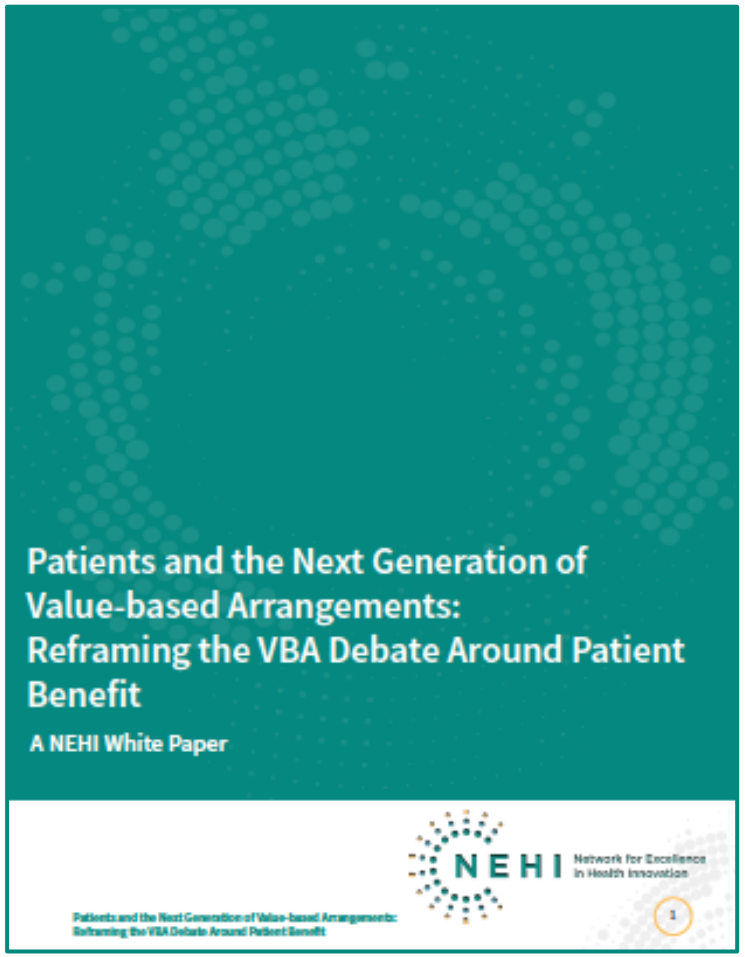
Approximately 5,000 "drug super spenders" incur $250,000 or more in annual prescription expenses, account for more than $2 billion in health plan drug costs.

MassHealth Negotiation Authority	Governor's Health Care Reform Bill (H.4134)	Senate Pharmaceutical Access, Costs and Transparency Act (S.2397)
July 2019 • CMS grants MassHealth authority to execute Medicaid VBAs • FY 2020 State Budget-new authority on drug negotiation ○ Annual pipeline assessment ○ Negotiation over supplemental rebates: drugs over $25k/utilizer or $10 million aggregate cost ○ Negotiation based on a proposed value ○ Stalemated negotiations may be referred to the Health Policy Commission (HPC) to determine value and reasonable price	• Center for Health Care Information and Analysis (CHIA) to conduct annual cost trend analysis of drugs • CHIA to issue annual review of gross costs per utilizer of all drugs approved in prior 5 years • Drugs costing $50k+ per year per utilizer referred to the Health Policy Commission (HPC) • HPC to establish a reasonable value for drugs referred to it; may mandate further disclosures from manufacturers • HPC to identify drugs with excessive prices • Oversight extended to PBMs	• System-wide drug pricing and spending to be reviewed at Health Policy Commission (HPC) Cost Trends Hearing • Manufacturers to provide early notice of novel drug launches • HPC to conduct confidential reviews of novel drugs with launch price over $50k • HPC to request "Access Improvement Plans" for drugs priced in excess of value determined by HPC

Value-based Arrangements: What are they?



MARCH 2019



OCTOBER 2020

VBA Takeaway Points

- “A tool in the payment toolbox”
- In limited use – address very specific issues between payers and manufacturers
- Interest in use of VBAs is high, but nearly all agreements are confidential
- Barriers:
  - Operational complexity
  - Regulatory constraints
    - Medicaid Best Price reporting
    - Anti-Kickback Statute enforcement

MAJOR GOALS	Payer	Manufacturer	Patients and Patient Communities
Scenario #1: Therapies for rare diseases and other diseases of small prevalence; ordinarily classified as specialty pharmaceuticals, includes drugs with high one-time costs	• Link net payments (including rebates) to results seen in Real World use • Recover costs if therapy fails in individual patients • Cushion initial budget impact of high-cost therapy (example: enable payment-over-time)	• Expedite payer's decision to cover therapy • Adapt utilization management requirements to facilitate access to novel drugs by providers and patients	• Prompt decisions on coverage by payers after drug's initial launch • Adapt utilization management requirements to facilitate prompt time-to-therapy • Financial protection against costs of therapy if therapy fails
Scenario #2: Therapies for chronic disease and other diseases of large prevalence (example: type 2 diabetes)	• Determine comparative effectiveness vs. preferred drugs • Lower total costs of care (medical and pharmacy) by increasing drug choices on formulary that enable optimal use of medicines by prescribers and patients	• Improve formulary position, lower barriers to access (or expand access) to drugs otherwise seen as interchangeable or commoditized	• Better affordability of therapies (example: reduce or eliminate out-of-pocket cost); reduced financial barrier to adherence and persistence • Improved access to drugs generating better treatment response vs. preferred drugs • Reduced disruption from non-medical drug switching

VBAs and Chronic Disease

Highmark, AstraZeneca Enter Outcomes-Based Agreement for Severe Asthma Medication Fasenra

Highmark announced that it has entered an outcomes-based agreement with AstraZeneca for Fasenra, an add-on prescription maintenance treatment for patients age 12 or older with severe asthma. Through outcomes-based agreements, drug companies are accountable for the clinical effectiveness of medications. As part of the agreement, Highmark is measuring members that stay on treatment signaling the treatment is working and the member's health is improving.

September 21, 2020

CMS Proposal for VBAs and Medicaid Best Price Reporting

An arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

- Evidence-based measures, which substantially link the cost of a drug to existing evidence of the effectiveness or potential value for specific uses of that product, and/or
- Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses."

Notice of Proposed Rule Making: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements, June 19, 2020

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THANKS FOR JOINING US

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